

REMARKS

Claims 1 and 37-95 are pending. Claims 2-36 are cancelled without prejudice or disclaimer. Claims 1, 37, 42, 43, 65, 79, 81, and 89 are amended for clarity. The terms "wear resistant" and "resists embrittlement" are added to further define and clarify the characteristics of the cross-linked UHMWPE, in claims 1, 37, 42, 43, 65, 79, and 89, are fully supported by the specification (see for example, the page 11, line 18 to page 12, line 17). The terms "wear resistant" UHMWPE and UHMWPE that "resists embrittlement" also are defined and described in the parent application serial no. 08/798,638, filed February 11, 1997, which is incorporated by reference in the specification (see page 1, lines 5-11), which also is the parent of US Patent No. 6,786,633. Therefore, no new matter has been added.

Claim Objections:

On page 2 of the Office Action, the Examiner has objected to claims 42 and 65-95 for various informalities and alleged that specification does not support a "three-cup prosthesis of a shell, acetabular cup, and a femur cup where the cup sizes are in the range of 35 mm to 70 mm." Applicants respectfully disagree with the Examiner and point out that the term "three-cup" is not present in the claim. However, the terms "shell, acetabular cup, and a femur cup" are fully supported by the specification. For example, see specification page 11, lines 8-10; page 13, lines 24-26; page 15, lines 30-35 provide support for medical prosthesis comprising / including polyethylene cups (*i.e.*, more than one cup) or shell (emphasis added). Applicants also refer to original claims, for example, claims 2, 21, and 24, that provide support that the claimed prosthesis comprising "a load bearing portion" and "a mating portion" (emphasis added). The claims also recite "at least one of the bearing portion", which clearly provide support for a shell and more than one cup, including an acetabular cup and a femur cup (emphasis added). Therefore, the terms "shell, acetabular cup, and a femur cup" used in the claims 42 and 65-95 are apparent from the descriptive portion of the specification.

The Examiner also alleges that there is no suggestion from the specification that embodiments in Figures 1 and 8 can be combined. Applicants disagree with the Examiner and point out that various aspects of the invention are disclosed in the

specification, including aspects that are depicted in Figures 1 and 8. In one embodiment of the invention in the "Description" applicants refer to "Fig. 1" (see for example, page 8, lines 23 to page 9 line 1), while in an "Additional Embodiment" applicants refer to "Fig. 8" (see for example, page 13, line 13 through page 15, lines 8-35). Therefore, claimed subject matter is supported throughout the specification, including the disclosure set forth in Figures 1 and 8.

Regarding claims 65, 79, and 89, applicants point out that the claims do not recite a three-cup prosthesis, although recite that the acetabular cup can embrace a femur cup or ball head. For additional clarity, applicants amend claims 65, 79, and 89 by replacing the term "and can embrace" with "to embrace."

In view of the above and clear support in the specification, withdrawal of the objections is earnestly requested.

Claim Rejections:

Indefiniteness Rejections

On page 3 of the Office Action, the Examiner has rejected claims 37, 39, 40, 42, 43, 45-65, and 67-78 and alleged that "range of about 35 mm to 70 mm does not have original support when it is combined with femur cup thickness of over about 5 mm." Examiner indicated that the specification (page 10, lines 1-27 and page 15, lines 8-22), disclose cup having "thickness in the 1mm to 5mm range." In response, applicants refer to the specification that discloses "cup thickness of about 6 mm or more" (see for example, page 2, lines 17-21), or a thickness "similar to conventional cup thickness" (see page 13, lines 15-26, which is know in the art to be of over about 5 mm).

On page 3, the Examiner also has rejected claims 81-88 and alleged that the specification lack support for a "diameter of 70 mm". Applicants disagree with the Examiner. Applicants state that the Examiner has referred to one aspect of the invention, wherein the small and mid-size sockets (page 17, Table-I) are disclosed. Applicants refer to the specification that discloses "head diameter may be larger than conventional heads [], the head diameter may be, e.g., greater than about 35 mm, preferably in the range of about 36 mm to about 70 mm, more preferably about 36 mm

to about 40 mm or about 40 mm to about 70 mm" (see for example, page 10, lines 13-21).

Withdrawal of the rejections is respectfully requested.

Obviousness Rejections

On pages 3-7 of the office action, the Examiner has maintained the obviousness rejections on claims 1 and 37-93 over various combinations of Graham *et al.* (U.S. Patent No. 5,549,700); Townley *et al.* (U.S. Patent No. 6,096,084); McKellop *et al.* (U.S. Patent No. 6,165,220); DeCarlo *et al.* (U.S. Patent No. 4,524,467); and Teinturier *et al.* (U.S. Patent No. 4,385,405). Applicants respectfully traverse these rejections.

Applicants state that the Examiner is looking at large head designs in the art and substituting the material employed with the cross-linked material of McKellop. The Examiner, however, is undertaking a post hoc rationalization of the art. The Examiner believes that McKellop provides motivation "in the abstract for crosslinking the polyethylene" thus to come up with the instant invention. Applicants respectfully disagree with the Examiner's views.

Applicants explain that, just because crosslinked polyethylene reduces wear in other context, as disclosed by McKellop, does not establish that it reduces wear in very large heads. Nor does McKellop establish that it reduces wear sufficiently with those large heads to avoid the pitfalls associated with the bone destruction (periprosthetic osteolysis), which particularly afflicts large heads when articulated against conventional polyethylene.

Crosslinked polyethylene according to McKellop reduces wear in small head sizes. McKellop, however, does not establish that crosslinking would reduce the wear of head sizes larger than 32 mm to a level that would be acceptable for use in humans. McKellop also does not establish that the independence of the wear rate from head size demonstrated between 22 and 32 mm would still be present if tested in 35, 36, 38, and 40 mm head sizes.

Therefore, McKellop in combination with any of the cited references would not arrive at the claimed invention. Withdrawal of the obviousness rejections is solicited.

Applicants also refer to the arguments submitted in response to the Office Action of March 4, 2004 (filed July 6, 2004). Applicants reiterate that: Graham does not teach the femur cup that can accommodate a femur head of 35 mm or greater; and Graham uses conventional UHMWPE.

Although McKellop mentions cross-linked UHMWPE, there is no disclosure supporting a cup that can accommodate a head of 35 mm or greater. Moreover, there is no motivation in McKellop to combine with Graham or Townley or DeCarlo or Teinturier. In countering applicants' previous arguments, the Examiner contended on page 7 of the Office Action that the "motivation is provided by McKellop in the abstract for crosslinking the polyethylene." However, Applicants reiterate that McKellop does not provide any motivation to crosslink a polyethylene for use in a cup that can "accommodate a head of 35 mm or greater," particularly given McKellop's reliance on smaller cups and head sizes.

McKellop does not describe acetabular cup having diameter of 35 mm or more, nor that the "crosslinked UHMWPE" could be used to make wear resistant acetabular cups that can accommodate femur head of diameter larger than 32 mm (see column 17, lines 3-4). McKellop reinforces the bias in the field for smaller heads (see Column 9, lines 65-67). McKellop's exclusive focus on 22-32 mm heads teaches away from making acetabular cup having diameter larger than 32 mm.

Regarding the Examiner's Response to Amendment:

On pages 7-8 of the Office Action, regarding Dr. Harris' declaration, the Examiner has made comments that there is "no actual proof" provided in Exhibit 1 that larger head sizes resulted in higher wear rate. Applicants disagree with the Examiner and state that the Examiner has not addressed the express statements in the prior art. Applicants further explain about head size that the evidence is overwhelming that with all previous materials used in total hip replacements, which include Teflon, conventional ultrahigh molecular weight polyethylene and Debrin. There was a direct relationship between the volume of wear produced and the size of the head. Large heads produce a greater volume of wear. Applicants point out, as submitted previously, Charnley, who invented total hip replacement surgery, was forced to go to smaller and smaller head

sizes despite the fact that his original proposed head size was 45 mm in diameter. Charnley was forced to do this because he found that the wear for the larger head sizes was excessive. This is well documented in his book (John Charnley, 1979, *Low Friction Arthroplasty of the Hip: Theory and Practice*, Springer-Verlag, Berlin, Heidelberg, New York, 1979. Pages 3-15, copy enclosed). See for example, Charnley describes "loading of a small-diameter ball can prevent 'third body' abrasion" (on page 6, right column, last paragraph), "small-diameter femoral head demanded by the theory of low frictional torque" (on page 13, left column, first paragraph), "general trend [] for designs of metal-to-plastic total hip to be moving towards the smaller ranges of femoral head (32, 28 and 25 mm)" (on page 14, right column, first paragraph).

Applicants summarize that, Charnley experienced the fact that large heads produce a greater volume of wear when he introduced Teflon type plastics. Charnley also observed the fact when switched to the conventional UHMWPE. The observation has subsequently been confirmed by a wide number of studies. For example, Livermore, *et al.* (American Journal of Bone & Joint Surgery 1990 (72) 4: 518-28) disclose that "[t]he greatest volumetric wear and mean rate of volumetric wear were seen with thirty-two-millimeter components", who studied the effect of femoral head size on wear of acetabular component made of conventional polyethylene (See page 518, Abstract).

Applicants point out that the Examiner has not addressed the statement in Dr. Harris' declaration that "results indicated higher volumetric wear rate increased with respect to size of femoral head", made based on Exhibits II-IX (filed July 6, 2004).

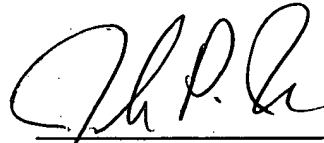
Applicants also point out that the Examiner has misunderstood Dr. Harris' previous declaration (filed July 6, 2004), especially, the difference between the linear wear rate and the volumetric wear rate. Therefore, applicants herewith submit another declaration of Dr. Harris clarifying linear versus volumetric wear, and that the invention has satisfied a long felt unmet need in the field.

REQUEST RELIEF

In view of above amendments and remarks, applicants respectfully submit that claims 1 and 37-95 are allowable, and respectfully request favorable consideration to that effect. The Examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,

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Date



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